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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,091	08/06/2003	Anne M. Pianca	05-00907-02	6980
23845 7590 01/16/2008 ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			MAIL DATE 01/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,091

Applicant(s)

PIANCA ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations "not movable with respect to each other" and "with no mechanical separation anywhere in the layer" are lacking support in the originally filed application. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis

for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10, 13-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gates et al. (US 5,522,875, hereinafter "Gates").

5. In regards to claims 1-3, 14, and 18, Gates discloses a lead/stylet combination (Fig. 1) wherein the stylet comprises an outer covering (201) and inner core (130) that are immovable with respect to each other (Figs. 15 and 16). Further, the inner and outer elements inherently possess different elastic and buckling properties because the inner core is made of 304 stainless steel (col. 7, line 54) and the outer covering is made of Nitinol (col. 9, line 45). The outer covering (201) is a continuous "sleeve" (Fig. 16) with no mechanical separation in the layer. Please note that the coil/core is the inner layer, not the outer layer.

6. In regards to claim 4, the outer covering defines a tube (Fig. 16) and the core is pre-formed because it is formed before implantation.

7. In regards to claim 5, the stylet is isodiametric over a portion of the length (Fig. 15).
8. In regards to claims 6, 7, 9, and 10, the outer covering has a variable wall thickness with respect to a single coil (i.e. the covering is thicker between windings of the coil than at the peaks of the coils) and is substantially constant over the gross stylet length.
9. In regards to claim 8, the stylet has variable outer diameter over a portion of it length, for instance the handle (Fig. 15).
10. In regards to claim 13, the core is pre-stressed because it is bent into a coil, thusly placing the inner surface of the coil in a compression state.
11. In regards to claims 16 and 20, the system is capable of DBS application because it is of a size capable of traversing blood vessels and will fit within the cranium.
12. In regards to claim 17, the outer covering defines an annulus because it "wraps around and covers" the core (col. 9, lines 34).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 11, 12, 15, and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Gates. Gates discloses the essential features of the claimed invention except for providing a composite stylet utilizing the claimed materials. It is well known in the implantable device arts to provide stylets and guidewires of the claimed material combinations to achieve desired torque, buckling, and bending characteristics for a specific implantation application. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Gates' stylet with the claimed material combinations to achieve desired torque, buckling, and bending characteristics for a specific implantation application.

Response to Arguments

16. Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. Applicant argued that the limitations "not movable with respect to each other" and "with no mechanical separation anywhere in the layer" are supported by the originally-filed application. The Examiner incorporates the arguments presented in the Office Action of 8/2/2007. Applicant asserted that the only disclosed embodiment is one

where a final assembled stylet has an inner core and outer covering that are not movable with respect to each other by virtue of the position that there is no discussion of a movable inner core; a movable inner core would be contrary to conventional stylets, and would have been discussed if this was a possible embodiment; and the manufacturing process of drawing the outer covering through a die would be unnecessary if the inner core were movable. For a limitation to be enabled, the limitation must either have explicit or inherent support from the originally-filed application. Mere silence of a feature that is contrary to the limitation is not enough. In other words, the position that the disclosure is lacking an embodiment where the inner core is movable is not germane to the question of whether an embodiment exists wherein the core is movable. Further, a movable core element is disclosed in paragraph 0043. For this limitation to be enabled, Applicant must rely on an inherent disclosure of immovability in the manufacturing process. Although the Examiner concedes that the manufacturing process does render the possibility that the two elements are immovable, there is nothing that makes this relationship inherent. See "Office Action of 8/2/2007." Regarding that limitation of "no mechanical separation anywhere in the layer," a similar argument applies: a disclosure lacking a positive recitation of mechanical separations is not grounds for exclusion. An explicit or inherent exclusion of mechanical separations must be set forth in the disclosure.

17. Further, Applicant argued that the inclusion of a stylet handle renders the possibility of a movable inner core impossible. However, the handle could have a hole

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in the center allowing insertion of the core, or the core could be inserted from the distal end of the stylet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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1/19/06

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GEORGE R. EVANISKO
EXAMINER

1/11/06